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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,378	08/21/2008	Sung Lan Hsia	117732-01601	1083
86738	7590	09/27/2011	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110				UNDERDAHL, THANE E
ART UNIT		PAPER NUMBER		
1657				
MAIL DATE		DELIVERY MODE		
09/27/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/597,378	HSIA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	THANE UNDERDAHL	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 27 June 2011.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) Claim(s) 100-118 is/are pending in the application.
  - 5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6) Claim(s) \_\_\_\_\_ is/are allowed.
- 7) Claim(s) 100-118 is/are rejected.
- 8) Claim(s) \_\_\_\_\_ is/are objected to.
- 9) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on 13 June 2008 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/11; 10/20/10; 7/21/09; 9/10/08; 7/08/08;</u>              | 6) <input type="checkbox"/> Other: _____                          |

*11/17/08*

### **Detailed Action**

This Office Action is in response to the Applicant's reply received 6/27/11.

Claims 100-118 are pending. No Claims are withdrawn. Claims 100-118 are considered on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 100, 102-106, 117 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (U.S. Patent # 5378461, issued 1995, In IDS 7/8/2008).

These claims are drawn to a method of treating melanoma in a subject comprising the following step:

- Topically applying a composition comprising 1 to 15% w/w of Coenzyme Q10 (CoQ10) for at least 30 days to the site of melanoma effective to reduce the growth of the melanoma.

The dependent claims limit that the subject is human. The composition is formulated as a cream or a liposomal composition. The concentration of CoQ10 is further limited to 1% to 10% w/w and even further to 1% to 5% w/w.

Claims 117 and 118 contain "wherein clauses" that limit the method of claim 100 either increases the apoptosis of the melanoma cells or inhibits melanoma-mediated angiogenesis. M.P.E.P 2111.04 state:

Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure

Furthermore since this is a method claim, patentability lies in the active steps. Prior art methods reading on all the active steps will inherently have the same results and physical properties (M.P.E.P 2112.02). Therefore these wherein clauses are given little patentable weight since they do not add a further step to the method but only recite an intended result of the method.

Neigut teaches a composition comprising 1-1.5% CoQ10 (col 10, lines 20-30 and col 15, lines 25-30). Neigut teaches that the composition is topically applied daily to the skin as a cream or ointment (col 9, lines 45-50) to humans (col 4, lines 20-25). Neigut teaches that the duration of the application can be as long as eight months with empirical observations to determine effectiveness (col 5, lines 45-50). Neigut teaches that their composition is liposomal in carriers such as lipids and surfactants like plant or animal oils, mineral oils, glycerin, propylene glycol, linolenic and linoleic acid (col 5, line 65 to col 6, line 5).

While Neigut does not expressly show the effects of their composition on melanoma, it would be obvious for one of ordinary skill in the art to use or at the very least try this composition on melanoma. This is because Neigut expressly teaches that

they believe applying their topical composition is effective for treating basal cell carcinoma and melanoma (col 7, lines 9-14).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 101, 107-108, 111, 113-116 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (U.S. Patent # 5378461, issued 1995) as applied to claims 100, 102-106, 117 and 118 above, and further in view of Nyce (WO 02/085297, published 2002).

Claim 101 is drawn to a method of treating melanoma in a subject comprising the following step:

- Topically applying for at least 30 days a composition comprising 1 to 15% w/w of Coenzyme Q10 (CoQ10) in an amount no more than 4.0 mg/kg of body weight to the site of melanoma effective to reduce the growth of the melanoma.

Claims 107-108, and 111 further limit the method of claim 100 by administering with the composition a chemotherapeutic agent selected from various drugs including verapamil. Claim 113 administers an anti-angiogenic agent with the composition. Claims 114-116 limit the order of administration of the composition and the agent.

While Neigut teaches topically administering daily a composition of 1-1.5% w/w CoQ10 to the site of melanoma on a subject, he does not teach that the upper dosage

limit is 4.0 mg/kg of body weight. Regardless this would have been obvious to one of ordinary skill in the art from the teachings of Nyce.

Nyce also teaches a topical composition of CoQ10 (ubiquinone) for the treatment of cancers (Nyce, pg 18, lines 30-35) such as melanoma (Nyce, pg 10, line 6). Nyce also teaches that the total dosage is about 1 mg/kg body weight per day (Nyce, pg 19, line 3).

Nyce teaches that their compositions can include anti-cancer agents such as the anti-cancer agents (Nyce, pg 19, line 26) and anti-angiogenic agents (Nyce, pg 20, line 1). Nyce teaches that these agents are incorporated into the composition with CoQ10 so are therefore co-administered.

Nyce does not teach that the anti-cancer agents are administered before or after the composition of CoQ10 as limited in claims 115 and 116. However M.P.E.P 2144.04 IV C state "selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results". Therefore it would have been obvious for one of ordinary skill in the art to rearrange the order of administration of CoQ10 and anti-cancer agents.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 109, 110, and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (U.S. Patent # 5378461) and Nyce (WO 02/085297) as applied to claims 101, 107-108, 111, 113-116 above, and further in view of either Lamson et al. (Alternative Medicine Review, 1999) or Lai et al. (U.S. Patent # 6093743, issued 2000).

Claims 109, 110 and 112 limit the anti-cancer agents to a list of chemotherapeutic agents including methotrexate, daunorubicin, doxorubicin, vincristine, vinblastine, tamoxifen and 5-fluorouracil. While Neigut and Nyce only teach specifically teach the chemotherapeutic agent verapamil, they do not teach any of the compounds listed in claims 109, 110, and 112.

Regardless this would have been obvious to one of ordinary skill in the art from the teachings of Lamson et al. who teach that along with CoQ10 many of the compounds listed in claims 109, 110 and 112 are already well known antioxidants for cancer therapy. Lamson et al. teach that cyclophosphamide, doxorubicin, vincristine, 5-fluorouracil (Lamson, pg 305, col 2 bottom) are already known in the art as anti-cancer agents, therefore it would be obvious to include them in the composition of Neigut and Nyce since these two references already include anti-cancer agents (MPEP 2144.06).

Alternatively this would also be obvious to one of ordinary skill in the art from the teachings of Lai et al. They too teach that many of the compounds listed in 109, 110, and 112 are known anti-cancer agents. They teach fluorouracil, tamoxifen, vinblastine, vincristine, daunorubicin and mitomycin (Lai, col 3, lines 5-20). Therefore it would be

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obvious to include these agents taught by Lai et al. into the composition of Neigut and Nyce since these two references already include anti-cancer agents (MPEP 2144.06).

No claims are allowable or free of the art.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure,** including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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